

### **REMARKS**

In the Office Action dated April 7, 2004, claims 20-26, 38-44 and 47-55 are pending and under consideration. Claims 20-26, 38-44 and 47-55 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 20-26, 38-44 and 47-55 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Thomson et al. (Science). Claims 20-26, 38-44 and 47-55 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 6,200,806 to Thomson.

Applicants wish to thank Examiner Voitach for the courtesy and assistance extended on behalf of Applicants during a telephone interview conducted on August 3, 2004.

Based on the Examiner's suggestions and in an effort to favorably advance the prosecution of the present application, Applicants have canceled claims 20-26, 38-44 and 47-55 and have added claims 56-63. Applicants reserve the right to pursue the subject matter of the canceled claims in a continuation application. In view of the cancellation of claims 20-26, 38-44 and 47-55, the rejections set forth in the Office Action are overcome. Withdrawal of the rejections is therefore respectfully requested.

Added claims 56-63 more clearly delineate the use of selected fibroblast feeder layer in determining the fate of undifferentiated pluripotent human stem cells in culture. Applicants respectfully submit that these added claims are fully supported by the specification. No new matter is introduced.

In the first instance, the ability of different fibroblast feeder layers in determining the fate of undifferentiated pluripotent human stem cells is described in the specification. For example, the type and handling of the fibroblast feeder layer is important for either maintaining the cells in undifferentiated state, or inducing differentiation of the cells. See, e.g., page 20, line

19; page 20, line 31 to page 21, line 3; and page 21, lines 4-19 and 22 of the specification. The Pera Declaration, submitted in the Response dated January 16, 2004, also demonstrates that different fibroblast feeders can be used for different purposes. See, e.g., Paragraphs 27-31 of the Pera Declaration. Therefore, by selecting the appropriate fibroblast feeder layer, either renewal of the cells, or differentiation into one or more somatic lineages, or differentiation into one or more extraembryonic lineages, or cell death, can be favored. See, e.g., page 21, lines 2-3; page 21, line 23 to page 22, line 5. As a result of employing a selected fibroblast feeder layer, a controlled differentiation (e.g., differentiation into one or more somatic lineages) can be achieved, and differentiation into extraembryonic lineages can be limited. Those skilled in the art would be able to select the appropriate fibroblast feeder layer for a desired purpose based on the present teaching.

The specification further teaches that, once the appropriate feeder layer is selected, other culture conditions or signals can be employed to favor differentiation of stem cells into somatic cells, which conditions do not cause stem cell death or differentiation into extraembryonic lineages. See, e.g., page 22, lines 3-19 of the specification.

Applicants further respectfully submit that the claimed subject matter, as presently recited, can be readily distinguished over the Thomson references. There is no recognition in either of the Thomson references that fibroblast feeder layers differ in their abilities of determining the fate of undifferentiated pluripotent human stem cells. Therefore, the Thomson references could not have possibly taught culturing stem cells on fibroblast feeder layers selected based on its ability to induce differentiation of stem cells, as presently claimed. The Thomson references merely teach that the fibroblast feeder layer is critical to maintain the stem cells in an undifferentiated state. See, e.g., Thomson (Science) at page 1146, left col., third paragraph.

In view of the foregoing amendment and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. DiGiglio', with a stylized flourish at the end.

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